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| APPLICATION NO. FILING DATE | | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|---------|------------|-------------------------|---------------------|------------------|
| 10/773,409 | | 02/09/2004 | Katsuhiro Hiejima | NPR-152 | 6612 |
| 20374 | 7590 | 11/01/2006 | | EXAMINER | |
| KUBOVC | K & KU | BOVCIK | KOHARSKI, CHRISTOPHER | | |
| SUITE 710 900 17TH S | TREET N | w | ART UNIT | PAPER NUMBER | |
| WASHING | TON, DC | 20006 | 3763 | | |
| | | | DATE MAILED: 11/01/2006 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| • . • | | Applicatio | n No. | Applicant(s) | | | | | |
|---|---|--|--|---|---------|--|--|--|--|
| | | 10/773,40 | Э | HIEJIMA, KATSU | HIRO | | | | |
| | Office Action Summary | Examiner | | Art Unit | | | | | |
| | | Christophe | r D. Koharski | 3763 | | | | | |
| | The MAILING DATE of this communic | ation appears on the | cover sheet with the o | correspondence ad | ldress | | | | |
| Period fo | | | S EVEIDE A MONTH | (C) OD TUIDTY (2 | ON DAVE | | | | |
| WHIC - Exter after - If NO - Failu Any r | ORTENED STATUTORY PERIOD FO CHEVER IS LONGER, FROM THE MA issions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this commu period for reply is specified above, the maximum stature to reply within the set or extended period for reply we reply received by the Office later than three months afted and patent term adjustment. See 37 CFR 1.704(b). | ALING DATE OF TH f 37 CFR 1.136(a). In no evenication. utory period will apply and will fill, by statute, cause the appli | IS COMMUNICATION Int, however, may a reply be tire expire SIX (6) MONTHS from cation to become ABANDONE | N. nely filed the mailing date of this c ED (35 U.S.C. § 133). | | | | | |
| Status | · | | | | | | | | |
| 1)🖾 | Responsive to communication(s) filed | on <u>20 October 2006</u> | 5. | | | | | | |
| 2a)□ | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | | |
| | closed in accordance with the practic | e under <i>Ex parte Qu</i> | ayle, 1935 C.D. 11, 4 | 53 O.G. 213. | | | | | |
| Dispositi | on of Claims | | | | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>1-25</u> is/are pending in the application. | | | | | | | | |
| , | 4a) Of the above claim(s) 11-19,21,23 and 25 is/are withdrawn from consideration. | | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | | | |
| 6)🛛 | Claim(s) <u>1-10,20,22 and 24</u> is/are rejected. | | | | | | | | |
| • | Claim(s) is/are objected to. | | | | | | | | |
| 8)[| Claim(s) are subject to restrict | ion and/or election re | equirement. | | | | | | |
| Applicati | ion Papers | | | | | | | | |
| 9)[| The specification is objected to by the | Examiner. | | | | | | | |
| 10) | 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | | |
| | Applicant may not request that any object | | | | | | | | |
| _ | Replacement drawing sheet(s) including | | | | | | | | |
| 11) | The oath or declaration is objected to | by the Examiner. No | te the attached Office | e Action or form P | 10-152. | | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | | | | |
| | Acknowledgment is made of a claim f ☐ All b)☐ Some * c)☐ None of: | or foreign priority und | der 35 U.S.C. § 119(a | a)-(d) or (f). | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| | application from the Internation | | | ad | | | | | |
| ^ ; | See the attached detailed Office action | i for a list of the certi | ned copies not receiv | eu. | | | | | |
| Attachmer | nt(s) | | | | | | | | |
| 1) 🛛 Notic | ce of References Cited (PTO-892) | _ | 4) Interview Summar | | | | | | |
| | ce of Draftsperson's Patent Drawing Review (Pirmation Disclosure Statement(s) (PTO/SB/08) | ГО-948) | Paper No(s)/Mail [5) Notice of Informal | | | | | | |
| | er No(s)/Mail Date 12/22/03, 1/13/05. | | 6) Other: | | | | | | |

DETAILED ACTION

Election/Restrictions

Claims 11-19, 21, 23 and 25 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (Group A selected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/20/2006. Currently claims 1-10, 20, 22 and 24 are pending for examination in this applicantio.

Specification

The abstract of the disclosure is objected to because it exceeds the 150-word maximum. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

The information disclosure statements (IDS) that were submitted on 12/22/2003 and 1/13/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

· A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakajima (US2002/01286044). Nakajima discloses an indwelling catheter assembly.

Regarding claims 1-9, 20 and 22, Nakajima discloses an indwelling catheter comprising a tube (2) a female connector (1) having a hollow form and an opening taper portion with tapers located in the body with a longitudinally slidably elastically deformable body located within the catheter body with an openable/closable portion (Figures 1-3 and 5-6) that deforms radially outward with a duckbill type configuration. Additionally, Nakajima discloses a connecting taper portion wherein the a male connector is inserted into the female connector causing the hemostasis valve to move forwardly wherein the inner needle (5a) is removable (Figures 1-3 and 5-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 24 is rejected under 35 U.S.C 103(a) as being unpatentable over Nakajima in view of Vaillancourt (6,699,221). Nakajima meets the claim limitations as described above except the express use of the male connector being a syringe.

However, Vaillancourt teaches a bloodless catheter.

Regarding claim 24, Vaillancourt teaches a syringe used with an inline vein puncture assembly (Figures 1-4, see summary of invention).

At the time of the invention, it would have been obvious to use a syringe with the system of Nakajima because it is well known in the art and Vaillancourt teaches that is that syringes are used with inline vein puncture assemblies. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Vaillancourt.

Claim Rejections - 35 USC § 103

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Claim 10 is rejected under 35 U.S.C 103(a) as being unpatentable over Nakajima. Nakajima meets the claim limitations as described above except for the elastic member being made of a rubber material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the seal of rubber, since there are many well known elastic materials in the art used construct seal and valve assmeblies, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/27/08

Christopher D. Koharski

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